

Risk Communication Advisory Committee

Meeting: November 12-13, 2009

Discussion Topics

FDA's Transparency Task Force

Please comment on the general topic of early communication about emerging safety issues concerning FDA-regulated products. The following two hypothetical situations may help start the discussion of the issue, but please note that our interest is in communication of emerging information in general, not the specifics of the hypothetical examples.

First Hypothetical Case Study: Early Communication about Emerging Safety Issues about FDA-Regulated Products

State and local public health authorities have been investigating an outbreak due to a foodborne pathogen. There are 18 illnesses primarily in one state with a few in a neighboring state. According to the human laboratory data, the same strain of pathogen caused all of the illnesses. One individual has died. The epidemiological investigation by the states found sandwiches and salads in common but no epidemiologic study is underway yet to implicate a specific food item.

1. Should FDA communicate this outbreak to the public? If so, what should the agency say? Is there anything that should not be communicated?
2. Should knowledge of the specific pathogen causing the outbreak influence the agency's decision?
3. Should the population that may be potentially exposed to the pathogen affect whether, and when, a message should be communicated?
4. How should FDA effectively communicate to consumers as the investigation evolves and new information changes the picture?

Second Hypothetical Case Study: Early Communication about Emerging Safety Issues about FDA-Regulated Products

There is an outbreak of a foodborne pathogen with 50 people ill in five states, many of whom have been hospitalized. State and local epidemiologists and CDC are investigating the human illnesses.

CDC alerts FDA that the epidemiological investigation conducted shows a link to fresh fruit salad consumed at various restaurants. Although recipes varied at the restaurants, three fruits were common to all of the salads consumed. Preliminary data suggests that cantaloupe is the cause. FDA contacts industry and they provide general distribution information indicating that cantaloupe is typically distributed nationwide. FDA has initiated a traceback of cantaloupe.

Produce trade associations have asked FDA and CDC for the information the agency has gathered about the source of the outbreak. These associations tell the agency that they can assist with the investigation if the agency provides them with more information about the outbreak.

(Note: Because the purpose of the discussion is to elucidate the policy considerations that should be weighed in deciding whether changes to current practice, laws, or regulations are warranted, the issues should be discussed without regard for the current practice, laws, or regulations.)

1. Should FDA advise the public about this outbreak? What are the factors that should be considered in deciding whether to do so? Is there anything that should not be communicated?
2. If the agency communicates to the public about the outbreak, what message should be communicated to consumers? What geographic area should be covered?
3. Should FDA communicate to members of industry whose products may be implicated in the outbreak? If so, what is the message?
4. How should FDA work with industry to address the outbreak?
5. Another entity, based on its own analyses, believes the outbreak is due to another fruit and releases a public statement to that effect. How should the agency respond?

Clinical Trials Database

1. How can we enhance public understanding of the limitations (listed below) of the trial-level data in the Results Database and minimize misinterpretation or inappropriate use of the data for purposes of health care decision-making? Some of the key concepts that need to be effectively communicated are
 - a. Data in ClinicalTrials.gov come from individual trials only and do not reflect the totality of relevant information about the topic at hand
 - b. Adverse events reported may or may not be caused by the intervention(s) under study
 - c. Trial and results information posted at ClinicalTrials.gov has not been reviewed or validated by NIH or FDA; in other words, the trial may or may not have internal or external validity for the questions that it is addressing
 - d. Results may or may not be statistically significant (or clinically relevant); even if statistical analyses are provided, they may or may not be appropriate
2. The tables of results data (including adverse events) at ClinicalTrials.gov are likely to be more comprehensible to individuals with clinical research expertise than to the lay public. What types of additional information would enhance public understanding of the results information and the context in which it must be considered? What are the effective ways of providing such information?
3. Considering the public display of clinical trial results, as currently presented in ClinicalTrials.gov, particularly outcome measure and adverse event information, should results information be displayed differently for the lay public? For example, should users be led through background information prior to seeing the results posted for a specific trial? If so, how could that information be best organized to assist members of the public in properly understanding the utility of the results of a single trial, taking into account the key concepts outlined in the first bullet above?